

GAMMA HEALTHCARE, INC.,
Plaintiff,

v.

ALEX AZAR, in his official capacity
as Secretary, United States Department
of Health and Human Services,

SEEMA VERMA, in her official
capacity as Acting Administrator for the
Center of Medicare and Medicaid Services,
AND

JEFF KAHRS, Deputy Regional Administrator
for (Region 7) the Center for Medicare
and Medicaid Services.

Defendants.

**ORDER ON EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER
AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF**

Case 6:20-cv-03337-MDH Document 18 Filed 10/28/20 Page 1 of 9

BACKGROUND

Plaintiff operates clinical laboratories located in Springfield, Missouri and Poplar Bluff, Missouri, which provide a variety of medical testing services. (Doc. 1). Until the events giving rise to this lawsuit, both labs operated under Clinical Laboratory Improvement Amendments (“CLIA”) certificates. (Doc. 12, 5). Defendants suspended Plaintiff’s federal authority to operate as clinical labs, effective October 26, 2020, pursuant to the Defendants’ authority to suspend Plaintiff’s lab certificates in advance of an administrative hearing. 42 U.S.C. § 263a(i) (Doc. 12, 1). Plaintiff’s Complaint raises the following claims: Injunctive Relief based on allegations of due process violations; Violation of Equal Protection Guarantees of the Fourteenth Amendment; and Violation of Due Process Guarantees of the Fourteenth Amendment.

“Labs like [Plaintiff] must meet certain federal standards in order to be certified to conduct diagnostic tests on human specimens (blood, tissue, and the like), and to receive Medicare or Medicaid reimbursement for their services. These standards are embodied in the Clinical Laboratory Improvement Amendments of 1988 (‘CLIA’ or ‘the Act’) and its implementing regulations. *See* 42 U.S.C. § [263a]; 42 C.F.R. Part 493.” *Wade Pediatrics v. Dep’t of Health & Human Servs.*, 567 F.3d 1202, 1203 (10th Cir. 2009). A lab’s compliance with these standards is memorialized in a “CLIA certificate,” which is subject to periodic reconsideration. Additionally, the Secretary of Health and Human Services’ designee may, on an announced or unannounced basis, enter and inspect any certified lab to determine whether the lab is, in fact, compliance with federal standards. 42 U.S.C. § 263a(g). If the Secretary determines the lab is out of compliance, the Secretary may impose sanctions. 42 U.S.C. §§ 263a(h)–(i). Sanctions may be mild or severe, including suspension or revocation of a lab’s federal certification. *Id.* Generally, the Secretary cannot suspend a lab’s federal certification before an administrative hearing, assuming the lab

wishes to contest the suspension. 42 U.S.C. § 263a(i). However, if the Secretary determines that a lab's failure to comply with federal standards presents an imminent and serious risk to human health, the Secretary may suspend the lab's certification prior to a hearing. 42 U.S.C. § 263a(i)(2).

Federal regulations govern how the Secretary's designees go about the important work of assessing which labs meet federal standards and which labs need to be pulled into compliance. 42 C.F.R. Part 493. Inevitably, most labs will fail to comply in some material way, but not all failures merit the same response. Federal regulations generally permit two categories of civil sanctions: (1) "principal sanctions," which are suspension, limitation, or revocation of the lab's certification; or (2) "alternative sanctions," which are government-directed plans of correction, state onsite monitoring, or civil money penalties. 42 C.F.R. § 493.1806. The two categories of sanctions get meted out against varying levels and patterns of noncompliance, and federal regulations generally guide the considerations in determining appropriate sanctions. 42 C.F.R. § 493.1804.

In cases of extreme and repetitive noncompliance, the regulations permit the Secretary to suspend a lab's certification prior to a hearing, on a mere five days' notice. 42 C.F.R. §§ 493.1812(b); 493.1840(d)(2). *Cf.* 42 U.S.C. § 263a(i)(2). If a lab's deficiencies pose "immediate jeopardy"—imminent and serious risk to human health and significant hazard to the public health—the lab must take immediate action. 42 C.F.R. § 493.1812(a). If the findings of a revisit to the lab indicate that the lab has not eliminated the imminent and serious risk to human health, the Centers for Medicare & Medicaid Services (CMS) suspends or limits the lab's federal certification. 42 C.F.R. § 493.1812(b). CMS must provide at least five days' notice, but it need not suspend a lab's federal certification in advance of a hearing. 42 C.F.R. §§ 493.1812(b), 493.1840(d)(2).

STANDARD

Before the Court can analyze the issues raised in Plaintiff's Motion for a Preliminary Injunction, the Court must first analyze whether it has jurisdiction over the claims raised in the Complaint. "The burden of establishing that federal jurisdiction exists 'rests upon the party asserting jurisdiction.'" *Midland Psychiatric Assocs., Inc. v. United States*, 145 F.3d 1000, 1003 (8th Cir. 1998) (internal citations omitted). A court must dismiss an action over which it lacks subject-matter jurisdiction. *Degnan v. Sebelius*, 959 F. Supp. 2d 1190, 1192 - 93 (D. Minn. 2013), *aff'd sub nom. Degnan v. Burwell*, 765 F.3d 805 (8th Cir. 2014).

DISCUSSION

The Court generally does not have federal question jurisdiction over any claim for Medicare or Medicaid payment (or nonpayment). *Cf.* 42 U.S.C. §§ 405(h), 1395ii (making § 405(h) applicable). This preclusion also extends beyond Medicare Act. "[C]laims arising under other statutes may be barred by section 405(h) if they are 'inextricably intertwined' with benefit determinations under the Medicare Act." *Clarinda Home Health v. Shalala*, 100 F.3d 526, 529 (8th Cir. 1996) (quoting *Heckler v. Ringer*, 466 U.S. 602 (1984)).

Federal question jurisdiction is barred unless the refusal to exercise such jurisdiction "would mean no review at all." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10–20 (2000) (explaining broad preclusion of federal jurisdiction over issues related to payments under the Medicare Act). In the Eighth Circuit, "[t]his exception applies where the litigant: (1) raises a colorable constitutional claim collateral to his substantive claim of entitlement; (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures." *Clarinda Home Health*, 100 F.3d at 530–31.

With respect to the second and third elements, Plaintiff argues that irreparable harm would result to it from the exhaustion of administrative remedies here, and the purposes of exhaustion would not be served here by requiring further administrative procedures. Specifically, the suspension would allegedly force Plaintiff's labs to close, as 65% of Plaintiff's revenue is dependent upon Medicare certification. (Doc. 17, 5). For their part, Defendants argue that the potential harm to Plaintiff is outweighed by public safety concerns. (Doc. 12, 32). Even if the Court assumes that irreparable harm and purposes of exhaustion elements are met in this case, the Court does not find that Plaintiff has raised a colorable constitutional claim collateral to its substantive claim of entitlement.

With respect to whether Plaintiff presents a colorable claim, Plaintiff suggests that its due process rights were violated due to the suspension. The key procedural due process question is the balance of Plaintiff's private interest, if any, against the process employed and the Government's interest. There is case law that suggests that procedural due process challenges to the pre-hearing suspension of CLIA certificates are not valid. *See, e.g., Collum v. Arkansas Dep't of Health & Human Servs.*, No. 4:06CV01496-WRW, 2007 WL 1238726, at *3 (E.D. Ark. Apr. 27, 2007); *D & G Holdings, LLC v. Leavitt*, No. CIV.A. 08-0373, 2008 WL 782446, at *1 (W.D. La. Mar. 20, 2008). Both cases declined to enjoin federal defendants suspending CLIA certificates in advance of a formal, adversarial administrative hearing. Both cases suggested that CLIA certificate holders lack a constitutionally protected property interest in a CLIA certificate, and, in any event, a pre-suspension, adversarial administrative hearing was not required in light of the regulatory notice and "some kind of hearing" procedures provided—referred to in the Supreme Court's seminal *Loudermill* decision as merely "an opportunity to respond" prior to deprivation of a protected property interest. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985).

Case law from the 8th Circuit suggests that Plaintiff lacks any property or liberty interest in a CLIA certificate. The Eighth Circuit's decision in *Key Medical Supply, Inc. v. Burwell*, 764 F.3d 955, 965 (8th Cir. 2014), held that Medicare providers have no "property interest that may serve as the basis of a due process violation." In *Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), the Eighth Circuit rejected a plaintiff's attempt to characterize a loss of business associated with a condition on Medicaid participation as a taking. There, the court stated, "[d]espite the strong financial inducement to participate in Medicaid," the care provider's choice to participate in Medicaid was "nonetheless voluntary." *Id.* The Eighth Circuit concluded, "[t]his voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation[.]" *Id.* *Minnesota Association of Health Care Facilities* controls in the present case. Plaintiff's procedural due process claim lacks merit due to the absence of a protected property or liberty interest in a CLIA certificate or federal healthcare program payments. Plaintiff's challenge is not "a *substantial* constitutional challenge capable of overcoming the bar on review." *Key Med. Supply, Inc.*, 764 F.3d at 965–66. *See also Koerpel v. Heckler*, 797 F.2d 858, 863–65 (10th Cir. 1986) (finding physician had no property interest in his eligibility for Medicare reimbursement); *Cervoni v. Sec'y of Health, Ed. and Welfare*, 581 F.2d 1010 (1st Cir. 1978) (finding plaintiff physician had no protectable property interest in his participation in Medicare).

Furthermore, the Defendants contend that due process was satisfied here, as Plaintiff was given notice prior to the suspension taking place. The Defendants did exercise their discretion to suspend Plaintiff's license with only 5 days' notice due to their determination that Plaintiff's labs posed "immediate jeopardy" to human health and the public. The 5 days' notice is provided for by

statute, as noted above. 42 C.F.R. § 493.1812(b). Additionally, the evidence suggests that Defendants first made a finding of immediate jeopardy regarding Plaintiff's labs in June of 2020. (Doc. 12, 13).

Moreover, the Court clearly lacks subject matter jurisdiction with respect to Plaintiff's claims here, because they are not collateral to the Plaintiff's claims that Defendants wrongfully suspended Plaintiff's licenses. Thus, Plaintiff's claims cannot satisfy the requirements that would allow this Court to exercise jurisdiction prior to Plaintiff exhausting its administrative remedies. A claim is collateral if it does not require the Court to "examine the merits of the underlying dispute, delve into the statute and regulations, or make independent judgments as to plaintiffs' eligibility under a statute." *Senior Life York, Inc. v. Azar*, 418 F. Supp. 3d 62, 71 (M.D. Pa. 2019) (quoting *Family Rehabilitation, Inc. v. Azar*, 886 F.3d 496, 503 (5th Cir. 2018)) (citing *Heckler v. Ringer*, 466 U.S. 602, 614 (1984); *Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 284-85 (5th Cir. 1999)). Collateral claims must present constitutional or procedural challenges and request temporary relief until the agency follows required procedures. *Family Rehab.* 886 F.3d at 503. (citing *Bowen*, 476 U.S. at 483; *Ringer*, 466 U.S. at 614; *Mathews v. Eldridge*, 424 U.S. 319, 330-32 (1976); *Affiliated Prof'l*, 164 F.3d at 284-85).

The "collateral" exception to the exhaustion of administrative remedies is not applicable to the claims in Plaintiff's complaint because they directly challenge Defendants' substantive determinations in imposing remedies against it. *See Cathedral Rock of North College Hill, Inc. v. Shalala*, 223 F.3d 354, 362 (6th Cir. 2000). As Defendants note, Plaintiff at no point alleges that Defendants did not follow their own procedural and statutory requirements in their decision to suspend Plaintiff's licenses. Additionally, Plaintiff does not identify a challenge to any particular regulation or statute. (Doc. 16, 2). Still, "governmental policies implemented through legislation

or regulations developed through presumptively reasoned democratic processes . . . should not be enjoined lightly.” *Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds*, 530 F.3d 724, 732 (8th Cir. 2008) (en banc).

Plaintiff’s Complaint invokes the merits of Defendants’ decision often. For example, the Verified Complaint reads under its Injunctive Relief Count:

98. [Plaintiff] disputes that the deficiencies identified in the October 7 and October 8 Surveys placed [Plaintiff’s] patients in Immediate Jeopardy. Nonetheless, [Plaintiff] resolved the deficiencies and has not yet been able to submit credible Allegations of Compliance demonstrating that both [Plaintiff’s] Springfield and Poplar Bluff laboratories removed the alleged Immediate Jeopardy and returned to substantial compliance with regulatory requirements before the suspension date.

(Doc. 1, 21).

Ultimately, Plaintiff requests the Court to second-guess Defendants’ statutorily authorized exercise of discretion in determining whether Plaintiff’s labs present a threat to public safety. Additionally, the law affords substantial deference to Defendants’ exercise of discretion in how Defendants go about achieving the statutory and regulatory objectives of certifying clinical labs. *See, e.g., S. Dakota v. U.S. Dep’t of Interior*, 423 F.3d 790, 799–800 (8th Cir. 2005) (describing the limits of APA review to agency action).

Plaintiff primarily relies on two cases to support its argument that it would be appropriate for the Court to intervene in this case prior to Plaintiff exhausting its administrative remedies: *Rockhill Care Ctr., Inc. v. Harris*, 502 F. Supp. 1227, 1229 (W.D. Mo. 1980) and *Lexington Mgmt. Co. v. Missouri Dep’t of Soc. Servs.*, 656 F. Supp. 36, 39 (W.D. Mo. 1986). First, *Rockhill* was implicitly overruled by both *Minnesota Association of Health Care Facilities*, 742 F.2d at 446 four years after it was decided and in 1985 by *Cleveland Bd. Of Educ. V. Loudermill*, 470 U.S. 532 (1985). Second, *Lexington* is distinguishable from the case at hand. The court in *Lexington* found that the action did not invoke § 405(g) or § 405(h), and importantly that the claims were wholly

collateral. *Lexington Mgmt. Co.*, 656 F. Supp. 36, 29. In that case, the plaintiff requested the court to enforce compliance with a provision of the Medicaid program. *Id.* Here, Plaintiff is not seeking to make Defendants comply with statutes or regulations—Defendants apparently followed them correctly—but rather Plaintiff seeks to challenge the merits of Defendants’ exercise of discretion pursuant to valid statutory authority. This is beyond the Court’s jurisdiction.

Because Plaintiff has failed to allege a colorable constitutional claim that is collateral to its claim of entitlement, Plaintiff has failed to establish that it should be entitled a waiver of the administrative exhaustion requirements.

CONCLUSION

Wherefore, for the reasons set forth herein, the Court **DENIES** Plaintiff’s Motion for Temporary Restraining Order and Preliminary and Permanent Injunctive Relief. The Court finds it does not have jurisdiction to review Plaintiff’s claims at this time. If, after exhausting any available administrative remedies, Plaintiff continues to seek review of its claims judicial review may then be appropriate.

IT IS SO ORDERED.

DATED: October 28, 2020

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE